IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC., and BAYER HEALTHCARE LLC,	)	
Plaintiffs,	)	
v.	)	**C.A. No. 05-349-GMS**
BAXTER INTERNATIONAL INC., and BAXTER HEALTHCARE CORPORATION,	)	
	)	**JURY TRIAL DEMANDED**
Defendants.	)	
BAXTER HEALTHCARE CORPORATION	)	
Counterclaimant,	)	**REDACTED VERSION DI 313**
v.	)	
TALECRIS BIOTHERAPEUTICS, INC., and BAYER HEALTHCARE LLC,	)	
Counterclaim Defendants.	)	

PLAINTIFFS' TRIAL BRIEF

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I. SUMMARY OF THE CASE

On June 1, 2005, Plaintiffs Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC (collectively, "Plaintiffs") brought this action against Defendants Baxter International Inc. and Baxter Healthcare Corporation (collectively, "Baxter") for infringement of United States Patent No. 6,686,191 ("the '191 patent"). The '191 patent issued on February 3, 2004, from an application filed on September 22, 1995 and names Dr. William R. Alonso as inventor. The patent claims a novel process for producing immune serum globulin ("ISG"), also known as intravenously injectable immune globulin or "IGIV", for intravenous administration to a patient. These lifesaving antibody drugs are used to treat patients suffering from immune deficiency including patients inflicted with diseases such as cancer and AIDS.

Claim 1, the only independent claim of the '191 patent, reads as follows:

> A method of treating a solution of antibodies which may have virus activity, the method comprising
>
> a) contacting the solution with a trialkylphosphate and a detergent under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of anticomplement activity; and
>
> b) then incubating the solution of step a) under conditions of controlled time, pH, temperature, and ionic strength, such that the increased anticomplement activity of the solution is reduced to an acceptable level suitable for intravenous administration[1].

Claim 1 is followed by 21 dependent process claims and 2 product-by-process claims. Baxter's process for manufacturing GAMMAGARD® LIQUID infringes claims 1, 7-10, 12, and 15-20 of the '191 patent in violation of 35 U.S.C. § 271(g). Baxter's infringement is willful and Plaintiffs are thus entitled to enhanced damages and attorneys' fees. 35 U.S.C. §§ 284, 285.

[1] For ease of reference, we refer to anticomplement activity, defined by the Court's claim construction Order (D.I. 199) as the "measure of the ability of antibodies to bind complement", as "ACA". We refer to the trialkylphosphate and detergents (such as cholate, polysorbate 80 and octoxynol) process step as the solvent/detergent step or "S/D" step.

Baxter denies infringement and alleges that the asserted claims of '191 patent are invalid for: (1) anticipation under 35 U.S.C. § 102; (2) obviousness under 35 U.S.C. § 103; (3) lack of written description under 35 U.S.C. § 112 ¶ 1; and (4) indefiniteness under 35 U.S.C. § 112 ¶ 2[2].

On December 28, 2006, the Court issued its claim construction order, rejecting Baxter's arguments and adopting Plaintiffs' proposed constructions. The Court found that most claim terms should be accorded their plain and ordinary meaning. Subsequently, Baxter filed a motion for summary judgment of invalidity for indefiniteness (D.I. 230), asserting that certain claim terms are indefinite. The motion has been briefed and is *sub judice*. Plaintiffs' motion to disqualify Baxter's counsel (D.I. 76) and Baxter's motion for leave to file an amended answer and counterclaim to add an inequitable conduct defense (D.I. 165) are also *sub judice*[3].

II. SUMMARY OF THE ISSUES

Baxter's process for manufacture of GAMMAGARD® LIQUID includes all the elements of claims 1, 7-10, 12, and 15-20 of the '191 patent. Baxter imported and sold GAMMAGARD® LIQUID in the United States after the filing of this lawsuit.

Baxter's invalidity defenses lack merit. First, the claims of the '191 patent are not indefinite as set forth in Plaintiffs' opposition to Baxter's summary judgment motion (D.I. 238). Second, the claimed invention is fully described in the '191 specification and satisfies the written description requirement. Third, the prior art does not anticipate or render obvious the asserted '191 claims because there is no express or inherent disclosure of S/D treatment elevating ACA. This is fatal to both Baxter's anticipation and obviousness defenses. No prior art recognizes or predicts the ACA elevation problem discovered by Dr. Alonso relating to the S/D viral

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[2] Baxter has waived its defense of lack of enablement under 35 U.S.C. § 112 ¶1.

[3] Because Baxter's belated inequitable conduct charges, as best we can understand them, are not properly issues in this case, we will refrain from further comment herein, reserving fully our rights to substantively answer these allegations in the event the same becomes necessary.

inactivation step and, therefore, none of the art could possibly anticipate or render obvious the claimed solution to this problem. At trial, Plaintiffs will also prove secondary indicia of non-obviousness, including, *inter alia*, commercial success.

Plaintiffs are entitled to a reasonable royalty for Baxter's infringement of the '191 patent. Baxter willfully infringed, warranting increased damages and attorney fees.

III. BAXTER'S INFRINGEMENT

Baxter infringes Claims 1, 7-10, 12, and 15-20 of the '191 patent, literally or under the doctrine of equivalence, by importing, offering to sell, selling, and using within the United States Baxter's GAMMAGARD® LIQUID product. 35 U.S.C. § 271(g).

A. Claim 1

1. Baxter Admits That Its Process Comprises "A Method Of Treating A Solution of Antibodies Which May Have Virus Activity".

REDACTED

Thus, the manufacturing process for GAMMAGARD® LIQUID contains "a method of treating a solution of antibodies which may have virus activity". The evidence fully supports this point.

2. Baxter Admits That Its Process Comprises "Contacting the Solution With A Trialkylphsophate and a Detergent".

REDACTED

3. Baxter Admits That Its Process Comprises An S/D Step That Is Performed "Under Conditions Sufficient To Substantially Reduce Any Virus Activity". At col. 2, lines 43-44 of the '191 patent, "substantial reduction" in virus activity is defined as a reduction of "at least 4 logs." The Court has construed the term "any virus activity" to have its plain and ordinary meaning, D.I. 199, which one of ordinary skill in the art understands includes especially lipid enveloped viruses that are inactivated by S/D, col. 1, lines 44-54.

REDACTED

4. Baxter's Process Comprises An S/D Step "Resulting In An Increased Level Of [ACA]".

REDACTED

4. Baxter's Process Comprises "Incubating the Solution of Step a) Under Conditions of Controlled Time, pH, temperature, and Ionic Strength".

REDACTED

REDACTED

5. Baxter's Process Comprises A Low pH Incubation Step "Such That The Increased [ACA] Of The Solution Is Reduced". Step b) of Claim 1 of the '191 patent states that the low pH incubation step should be performed "such that the increased [ACA] activity of the solution is reduced."

REDACTED

6. GAMMAGARD® LIQUID Has An "Acceptable [ACA] Level Suitable For Intravenous Administration". Since it is undisputed that GAMMAGARD® LIQUID is currently approved for sale worldwide by regulatory agencies and marketed for intravenous administration to human patients, this product has an "acceptable [ACA] level suitable for intravenous administration."

Because all the claim limitations are met, Baxter infringes claim 1.

B. Claims 7-10

Claim 7 depends from Claim 1, adding the further limitation that the controlled incubation is "for at least about 10 days."

REDACTED Claim 8 of the '191 patent states that the incubation step of claim 1 is performed so that "the pH is maintained within range of

about 3.5 to about 5.0." REDACTED

Claim 9 of the '191 patent states that the incubation step of Claim 1 is performed so that "the temperature is maintained within a range of 2°C to 50°C."

REDACTED

Claim 10 states that the incubation step of Claim 1 is performed so that "the ionic strength is less than about 0.001 M." The evidence establishes that, as properly calculated, the ionic strength of Baxter's product is "less than about 0.001M". Further, if additional incidental ions are included in the calculation, the ionic strength is still sufficiently low that it will function in the same way to result in a lowering of the ACA, as recited in claims 1 and 10, and thus would be functionally equivalent to, and insubstantially different from, a solution having an ionic strength of less than about 0.001M. Baxter infringes Claim 10 literally or under the doctrine of equivalents.

C. **Claims 12, 15-20.**

Claim 12 of the '191 patent states that the method of claim 1 includes a step that adjusts "the tonicity of the solution to a physiologic value under such conditions that the ionic strength is not appreciably altered."

REDACTED

Baxter's method for manufacturing GAMMAGARD® Liquid involves "adjusting the tonicity of the solution to a physiologic value under such conditions that the ionic strength is not appreciably altered," as required by Claim 12. Claim 15 states further that the tonicity of the solution of Claim 12 should be "adjusted to a range of about 230 to about 490 mOsmol/kg solvent," while

Claim 16 requires a range of 274 to about 309 mOsmol/kg solvent. Baxter infringes Claims 12, 15 and 16 either literally or under the doctrine of equivalents.

Claim 17 of the '191 patent states that the tonicity of the solution of Claim 12 is "adjusted by adding an amino acid to the solution." Claim 18 states that the amino acid used for the tonicity adjustment of Claim 17 is glycine

REDACTED

Baxter, therefore, adjusts the tonicity of GAMMAGARD® Liquid with the amino acid glycine. Baxter infringes Claims 17 and 18.

Claim 19 of the '191 patent claims the method of claim 1, "wherein the trialkylphosphate is tri-n-butyl phosphate and the detergent is selected from polysorbate 80 and sodium cholate."

REDACTED

Baxter infringes Claim 19.

Claim 20 of the '191 patent states that step a) of claim 1 (the solvent/detergent treatment) is performed at a pH of between about 3.5 and about 6.0.

Baxter infringes Claim 20.

D. The '191 Patent Is Neither Anticipated Nor Rendered Obvious By The Prior Art.

The '191 patent is presumed valid, 35 U.S.C. § 282, and Baxter must prove invalidity by clear and convincing evidence. To prove that a claim is anticipated by the prior art, Baxter must prove that: (1) the publications that it relies on are in fact prior art and (2) a single alleged prior art reference discloses or contains every element of the claim, either expressly or inherently. *Verdegall Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). A prior art

reference also may inherently anticipate if the claimed invention is always present in the prior art reference, *i.e.*, if it always results from the practice of that prior art. *In re Robertson,* 169 F.3d 743, 745 (Fed. Cir. 1999). "Inherent anticipation requires that the missing descriptive material is 'necessarily present', not merely probably or possibly present in the prior art." *Trintec Indus., Inc. v. Top-U.S.A., Corp.,* 295 F.3d 1292, 1295 (Fed. Cir. 2002) (citations omitted).

REDACTED

A patent claim is invalid as obvious under 35 U.S.C. § 103 "if the differences between the subject sought to be patented and the prior art are such that the subject as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103; *Merck, Inc. v. Teva Pharm. USA, Inc.,* 395 F.3d 1364, 1372-78 (Fed. Cir. 2005). Unlike anticipation, an obviousness inquiry can involve examining the combination of elements in multiple prior art references. The ultimate determination of obviousness is a question of law that turns on the underlying facts. *Sandt Tech. Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1354 (Fed. Cir. 2001). **REDACTED**

REDACTED

Moreover, in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, (2007) the Supreme Court reaffirmed the principle that a "hindsight bias" and "arguments reliant upon *ex post* reasoning" are improper. *Id.* at *17. However, hindsight is precisely the approach Baxter's expert used to perform his obviousness analysis.

REDACTED

Because Baxter cannot prove that the prior art either expressly or inherently discloses elevation of ACA as a result of S/D treatment (*see infra*), Baxter cannot establish even a *prima facie* case of obviousness, let alone the required clear and convincing case. Considering the opinion of Plaintiffs' Dr. Ravetch that the claims of the '191 patent are not obvious, and the evidence that Plaintiffs intend to present at trial, including "secondary considerations of nonobviousness" such as: (1) commercial success of the invention; (2) long felt, but unsolved need; and (3) failure of others, Baxter's obviousness claim is devoid of merit.

1. Written Description

The '191 patent fully describes the claimed process in such a way that one of ordinary skill in the art would understand that the patentee was in possession of the claimed invention. *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000).

Dr. Alonso was in possession of the invention with respect to the term "trialkylphosphate and a detergent". The '191 specification incorporates by reference the Neurath patent, (U.S. Patent No. 4,540,573), which describes S/D treatments in detail. The '191 patent also includes a detailed description of the S/D treatment. Moreover, to fulfill the written description requirement, the patentee does not have to describe techniques that were already in the prior art and well-known to those of ordinary skill in the art. *Space Systems/Loral, Inc. v. Lockheed Martin Corp.*, 405 F.3d 985, 987 (Fed. Cir. 2005).

REDACTED

Step a)'s "under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of [ACA]" is also fully described. One of ordinary skill in the art would understand that S/D treatment primarily is effective against lipid-enveloped viruses.

REDACTED

The '191 patent itself also describes multiple S/D conditions that elevated ACA, including, but not limited to, TNBP/Tween (polysorbate 80) and TNBP/cholate at pH 5.8. The '191 patent fully illustrates that the patentee was in possession of the invention with respect to the terms "under conditions…resulting in an increased level of [ACA]". For example, Table 1 and the text in column 8 both demonstrate fully the previously unknown and unrecognized phenomenon that S/D treatment, under the conditions tested, results in an unexpected increase in ACA.

Baxter's argument about the term "the increased [ACA] of the solution is reduced to an acceptable level of [ACA]", relies upon its rejected claim construction that there can be no intervening steps between the S/D treatment and the low pH incubation step. Baxter also argues that ACA levels immediately before incubation must be precisely the same as they were immediately following S/D treatment. There is no such requirement in the claims. This argument is contrary the Court's claim construction Order, which allows for intervening processing steps, contrary to the '191 specification, and contrary to the art.

The '191 patent teaches that the patentee was in possession of the invention with respect to the term "the increased [ACA] of the solution is reduced to an acceptable level of [ACA]". Table 3 shows ACA values for samples immediately before and immediately after the claimed incubation and shows that the low pH incubation step (step b)) reduces ACA. Table 5 shows the initial ACA values immediately preceding the final incubation (both are >100 CH_{50} units/mg, which is then lowered to 49 (22°C) and 71 (5°C), respectively), demonstrating that the incubation step lowers ACA. Table 6 shows the effect of extended incubation on ACA, demonstrating that extended incubation results in a continuous lowering of ACA. Table 7 shows that 21-day incubations result in lower ACA values than 10-day incubations.

As to the term "reduced to an acceptable level suitable for intravenous administration," the '191 patent repetitively exemplifies that the claimed process can lower elevated ACA levels. *See, e.g.*, '191 patent, Table 7. The specification also lists as preferences and examples, levels of ACA in the patentee's products considered to be acceptable for those products and processes, and illustrates how the '191 process is employed to achieve those exemplary acceptable levels.

2. Indefiniteness

Defendants cannot prove at trial that the following claim terms at issue are indefinite. Baxter argues that "acceptable level suitable for intravenous administration" is indefinite. Yet, it

is undisputed that Baxter's GAMMAGARD® LIQUID product has an acceptable level of ACA suitable for intravenous administration. It is approved by regulatory agencies and sold for such use. An "acceptable level suitable for intravenous administration" can be determined on the basis of data that are used by manufacturers to establish release specifications for the final product. These release specifications, which must be approved by FDA, are derived through an iterative process between the particular manufacturer and the particular regulatory authority based on, among other things, an exhaustive review of extensive clinical data. Every manufacturer of IGIV products knows what an acceptable level of ACA suitable for intravenous administration is for its particular product and process, and every expert in this case had no problem understanding its meaning, whether it be in the context of the prior art or Baxter's accused product.

Baxter argues that the term "increased level of [ACA]" in step a) is indefinite because, assuming the patent does not require an increase in ACA to an unacceptable level, the subsequent claim term in step b), "reduced to an acceptable level," would have no meaning since the ACA before incubation would already be acceptable. Baxter's argument hinges on a reading of the this claim term that the Court specifically rejected. *See* D.I. 199 n.4. Step a) only requires an increase in ACA levels, and step b) requires a reduction in ACA levels – the scope of these terms is quite clear. Only the ACA level in the final solution has to be acceptable. That the final solution must have acceptable ACA does not require unacceptable ACA levels prior to incubation. This term is sufficiently definite such that one skilled in the art would understand the bounds of the claim when read in light of the specification – an increase in ACA resulting from S/D treatment.

Baxter also argues that the term "then incubating the solution of step a)" and "increased [ACA] of the solution" found in claim 1 are indefinite. The Court construed "increased [ACA] of the solution" to have its plain and ordinary meaning and construed "then incubating the solution of step a)" to mean "incubating a solution originating from step a) under conditions of controlled time, pH, temperature, and ionic strength, wherein additional steps may be performed prior to said incubating". Baxter argues that because the additional processing steps allowed by the claim may result in a different "solution" with a different ACA level being incubated, it would no longer be "the increased ACA of the solution" as required by step b).

REDACTED

Baxter's argument runs afoul of the Court's claim construction and knowledge in the art.

IV. DAMAGES

Plaintiffs are entitled to a reasonable royalty on Baxter's sales of GAMMAGARD® LIQUID for Baxter's infringement of the '191 patent. 35 U.S.C. § 284. The parties have agreed that Baxter will provide updated sales information prior to trial so that the current royalty base may be accurately established. Plaintiffs have also requested a permanent injunction barring the sale of Baxter's GAMMAGARD® LIQUID. Under *eBay, Inc. v. MercExchange, LLC*, 126 S. Ct. 1837, 1839 (2006), a permanent injunction is no longer automatically granted in patent cases. Thus, a reasonable royalty must be determined based on a hypothetical negotiation in which there are two scenarios, one in which Baxter is enjoined from selling GAMMAGARD® LIQUID, and one in which Baxter is not enjoined.

If an injunction is issued, Plaintiffs are entitled to a reasonable royalty from September 26, 2005 to the date the injunction is issued **REDACTED**

In this instance, the reasonable royalty should be based on the

circumstances leading up to the injunction. However, should the Court find that Plaintiffs are not entitled to an injunction, Plaintiffs will be forced to compete in the market against a competitor (Baxter's GAMMAGARD® LIQUID) who has been granted a compulsory license to its technology. The reasonable royalty in this non-injunction scenario must compensate Plaintiffs not only for the past damages incurred, but also any future damages that result from Baxter's continued presence in the market with a competitive liquid IGIV product. Thus, the reasonable royalty in the non-injunction scenario will be a higher royalty rate in order to compensate Plaintiffs for its likely future lost sales. **REDACTED**

The term of this license would be through the expiration of the patent, July 29, 2020.

Plaintiffs should receive treble damages for Baxter's willful infringement of the '191 patent. *See* 35 U.S.C. § 284 (2004). A party's infringement is willful if it knows about the asserted patent before making, using, or selling the accused product and then proceeds without a good faith belief that the asserted claim is invalid or that the accused product does not infringe. *Great N. Corp. v. Davis Core & Pad Co.*, 782 F.2d 159, 166-67 (Fed. Cir. 1986

REDACTED

Plaintiffs filed suit against Baxter on June 1, 2005 and Baxter nonetheless launched its product on September 29, 2005, after being sued. Baxter's lack of a reasonable, good faith belief is borne out by the totality of the circumstances

REDACTED

See Minco, Inc. v. Combustion Eng'g, 903 F.Supp. 1204, 1221-22 (E.D. Tenn. 1995). Because Baxter's infringement is willful, the Court should declare this case is

exceptional and award Plaintiffs enhanced damages and reasonable attorneys' fees. 35 U.S.C. §§ 284, 285 (2004); *SRI Int'l, Inc. v. Advanced Tech. Labs.* 127 F.3d 1452, 1468 (Fed. Cir. 1997).

V. ANTICIPATED MOTIONS FOR DIRECTED VERDICT

Plaintiffs anticipate moving the Court to direct entry of judgment as a matter of law on infringement at the close of Plaintiffs' case and after Baxter's case in chief on the theory that, based on the evidence presented, no reasonable jury could fail to find infringement of the asserted claims or could find those claims invalid. *See* Fed. R. Civ. P. 50(a). Plaintiffs anticipate renewing its motion at the end of all of the evidence. *See id.* If for any reason the jury finds for Baxter, contrary to the evidence, Plaintiffs also anticipate renewing their request for judgment as a matter of law or requesting a new trial . *See id.* at 50(b) and 59.

Respectfully submitted

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CERTIFICATE OF SERVICE

I hereby certify on this 14th day of May, 2007 I electronically filed the foregoing **Plaintiffs' Trial Brief** with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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I also hereby certify that a true copy of the foregoing document was served upon the following in the manner indicated on May 14, 2007.

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